BENEPATCH- lidocaine hydrochloride, menthol patch
Meds Direct Rx, Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BenePatch (69418-002)

ACTIVE INGREDIENTS:

Lidocaine HCL 4.00%
Menthol 1.00%

Topical Anesthetic
External Analgesic

USES:

For temporary relieft of pain associated with minor cuts, scrapes and minor skin irritations.

WARNINGS:

- For external use only.
- Avoid contact with eyes.
- Do not apply on open wounds or damaged skin.
- If symptoms persist for more than seven days, discontinue use and consult physician.
- Do not bandage tightly.
- If pregnant or breast-feeding, contact physician prior to use.
- Do not use in large quantities, particularly over raw surfaces or blistered areas.

Keep out of reach of children.

If swallowed, consult physician.

DIRECTIONS:

- Clean and dry affected area.
- Remove patch from backing and apply to affected area.
- Use only one patch at a time, and maximum of four patches/day.
- Leave patch on affected area for up to 8 hours.
- Do not use patches for longer than 5 consecutive days.
- Children under 12 should consult physician prior to use.

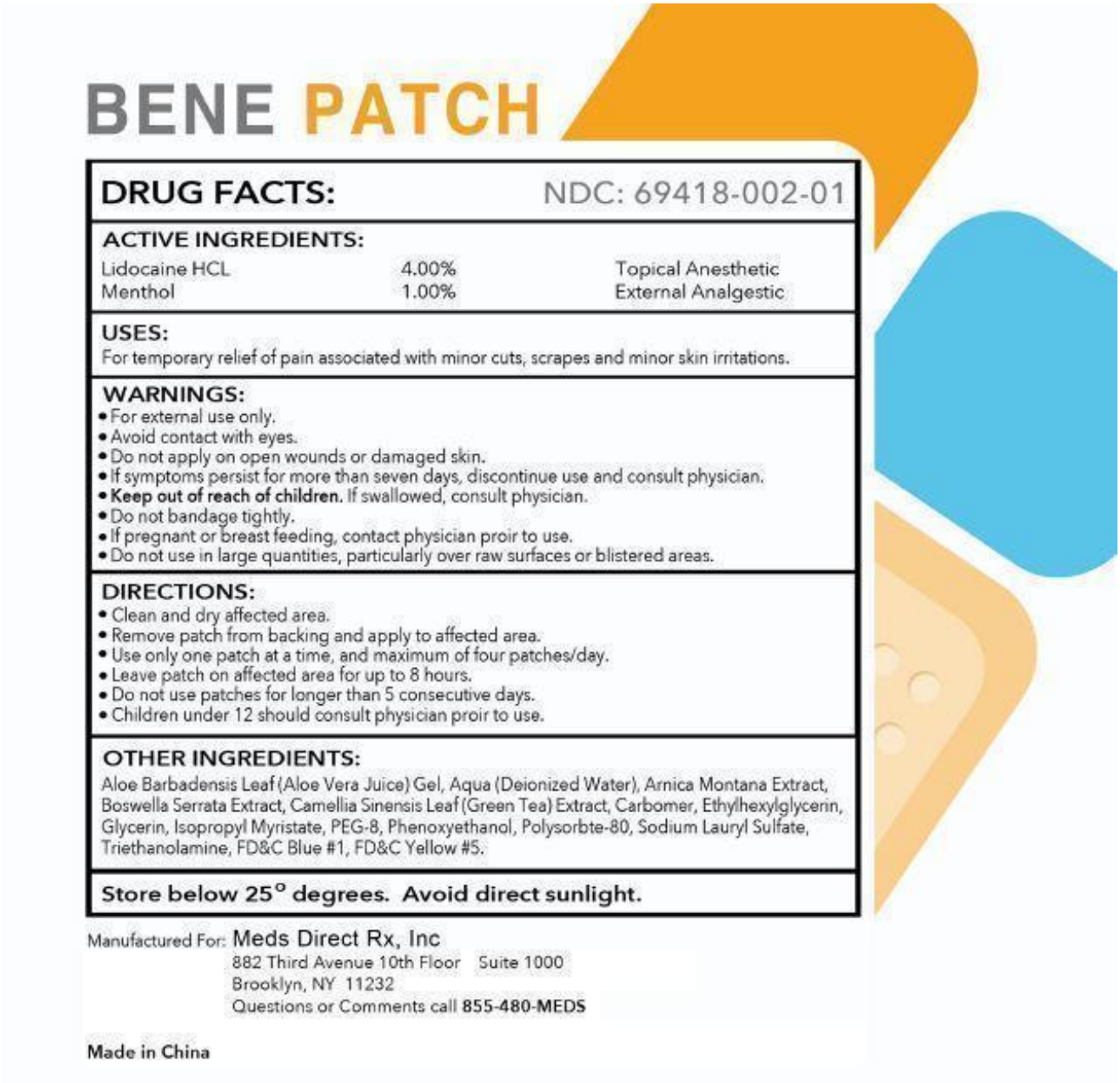
OTHER INGREDIENTS:

Aloe Barbadensis Leaf (Aloe Vera Juice) Gel, Aqua (Deionized Water), Arnica Montana Extract, Boswellia Serrata Extract, Camellia Sinensis Leaf (Green Tea) Extract, Carbomer, Ethylhexylglycerin, Glycerin, Isopropyl Myristate, PEG-8, Phenoxyethanol, Polysorbate-80, Sodium Lauryl Sulfate, Triethanolamine, FD&C Blue #1, FD&C Yellow #5.

Package Labeling for BenePatch, 15 Count (69418-002-01)

NDC: 69418-002-01

BENE PATCH



BENEPATCH

lidocaine hydrochloride, menthol patch

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:69418-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	1 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	4 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TROLAMINE (UNII: 9O3K93S3TK)	
ARNICA MONTANA (UNII: O80TY208ZW)	
INDIAN FRANKINCENSE (UNII: 4PW41QCO2M)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics			
Color		**Score**	
Shape	RECTANGLE (patch)	**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69418-002-01	3 in 1 BOX		
1		5 in 1 POUCH		
1		15 g in 1 PATCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/24/2015	

Labeler - Meds Direct Rx, Inc. (064053428)

Establishment

Name	Address	ID/FEI	Business Operations
Foshan Aqua Gel Biotech Co. Ltd		529128763	manufacture(69418-002)

Revised: 11/2015 Meds Direct Rx, Inc.